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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,239	02/27/2002	Simon Ward	674569-2001	1714

20999 7590 11/02/2005  
FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER

ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/085,239	WARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 40-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-42 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>March 30, 2005</u>  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

#### **Claims 40-42 are presented for examination.**

Applicant's Amendment filed August 10, 2005 and Information Disclosure Statement (IDS) filed March 30, 2005 have each been received and entered into the application. Accordingly, the specification at pages 23, 27, 29, 31-33, 56, 57, 73, 76 and 120 has been amended and claims 40-42 have each been amended and claim 43 is newly added.

In light of the above amendments and accompanying remarks, the objections to the specification to include the alternative spelling of the word "disulphiram" and the objections enumerated at pages 7-8 as (i)-(ix) have each been withdrawn have been hereby **withdrawn**.

In view of the cancellation of the subject matter drawn to the other active agents in claim 40, the rejection of claims 40-42 under 35 U.S.C. 102(b) as set forth at pages 7-8 and 10-11 is rendered **moot** and is hereby **withdrawn**.

As reflected by the attached, completed copy of form PTO-1449 (one page total), the Examiner has considered the cited references.

#### ***Allowability of the Instant Claims as Noted in the Previous Office Action***

Regrettably, the indicated allowability of the instant claims as indicated in the previous Office Action dated February 10, 2005 is hereby **withdrawn** by the Examiner in view of the newly discovered reference(s) to Burchardt et al. Rejections based on the newly cited reference(s) follow.

The Examiner has noted Applicant's request for an interview. Applicant is invited to contact the Examiner to arrange a mutually convenient date and time to discuss the rejections of record presented below in the instant Office Action regarding the present claims.

***Objection to the Claims (New Ground of Objection)***

Claim 43 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Objection to the Specification***

Applicant's amendment filed August 10, 2005 fails to cure the defect noted at page 18, line 17 and page 41, line 2. The disclosure remains objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 18, line 17 and page 41, line 2. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01.

***Claim Rejection - 35 USC § 102 (New Ground of Rejection)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Burchardt et al. (WO 97/15298, 1997; cited by Applicant on the IDS filed March 30, 2005).

Burchardt et al. teaches the treatment of acute and chronic inflammatory disorders, such as psoriasis (page 6, lines 1-11; see present claims 40-42), using a glucocorticosteroid, such as carbenoxolone sodium (see present claims 40-42), and an LTD4 receptor antagonist (page 1, lines 4-6 and page 2, lines 3-7).

It is noted that Burchardt et al. teaches the concomitant use of an LTD4 receptor antagonist with carbenoxolone sodium, but Applicant is reminded that the present claims use the word “comprising”, which is considered open transitional claim language and allows for the use of other components with the active agents recited in the present claims (see MPEP §2111.03 [R-2] for a discussion of transitional phrases). Thus, the present claims do not patentably exclude the additional components, such as the LTD4 receptor antagonist of Burchardt et al. Regardless of whether Burchardt et al. further discloses the concomitant use of another active agent, such does not change the fact that Burchardt et al. expressly teaches the use of carbenoxolone sodium for the treatment of psoriasis.

***Rejection of the Present Claims Over Bandman et al. (U.S. Patent No. 5,858,750) in View of***

***Vuligonda et al. (U.S. Patent No. 5,917,082) Is Not Made***

Performance of a prior art search directed at the inventive concept(s) of the present claims uncovered U.S. Patent No. 5,858,750 (1999) to Bandman et al., entitled “Human Retinol Dehydrogenase Type II Homolog”. However, a rejection over this reference was not made because it appears that the state of the prior art was such that the use of carbenoxolone, a

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compound known to inhibit retinol dehydrogenase, for the treatment of acne vulgaris, actinic keratosis, solar keratosis, squamous carcinoma, ichthyoses, hyperkeratosis or Darrier's disease, would not have been obvious to one of ordinary skill in the art at the time of the present invention.

Bandman et al. teaches that retinol dehydrogenase (RoDH) catalyzes the conversion of retinol to retinal, which is converted to retinoate, a retinoid compound, via retinal dehydrogenase (see Bandman et al., col.1, lines 31-35). Bandman et al. states that the second isoform of retinol dehydrogenase, RoDH(II), is inhibited by the active agent carbenoxolone (col.1, line 67-col.2, line 3) and further teaches that HRoDH appears to play a role in disorders associated with immune response, cell proliferation and development (col.18, lines 31-33). Bandman et al. states the following diseases or disorders are associated with the expression of HRoDH: xeroderma pigmentosum, photoaging, actinic keratosis, basal cell carcinoma or acne vulgaris (col.27, line 9-66). It is clear from the teachings of Bandman et al. that such disorders are associated with abnormal expression of HRoDH, but the reference fails to clearly define whether such conditions are associated with overexpression or underexpression of HRoDH.

An additional search of the prior art reveals that compositions having a retinoid-like compound or compounds as the active ingredient are useful as regulators of cell proliferation and differentiation, particularly for treating mammals for numerous diseases and conditions, such as skin-related diseases (i.e., actinic keratosis, acne, psoriasis, ichthyoses and other keratinization and hyperproliferative disorders of the skin, Darrier's disease, skin cancer, etc.). See Vuligonda et al. (U.S. Patent No. 5,917,082; June, 1999) at column 1, lines 32-59.

Considering that compositions having retinoid-like activity were known in the art to have efficacy in regulating cellular proliferation and differentiation in mammals suffering from keratinization and hyperproliferative disorders of the skin, it would appear that the prior art would actually teach away from using a compound such as carbenoxolone, since such a compound was known in the art to inhibit retinol dehydrogenase. Inhibition of retinol dehydrogenase would consequently inhibit the conversion of retinol to retinal, which would inhibit the production of retinoate, a retinoid compound. In the absence of retinoid(s) or retinoid-like active compounds, regulation of cell proliferation and differentiation could not occur according to Vuligonda et al., since such retinoid compounds are known to regulate the proliferation and differentiation of cells, especially those associated with the skin disorders actinic keratosis, acne, psoriasis, ichthyoses and other keratinization and hyperproliferative disorders of the skin, Darrier's disease or skin cancer (see Vuligonda et al., col.1, lines 32-59).

In light of such teachings, it would, therefore, be erroneous to conclude that it would have been obvious to one of ordinary skill in the art to employ a retinol dehydrogenase inhibiting compound, such as carbenoxolone, in the treatment of skin disorders known to be responsive to retinoid(s), since the effect of a retinol dehydrogenase inhibiting compound would be to inhibit the very production of retinoid. It would have been apparent to the skilled artisan, in light of such knowledge, that a therapeutic modality that fails to produce retinoid(s) or retinoid-like activity (i.e., the presently claimed agent carbenoxolone) would not demonstrate efficacy in treating skin disorders, such as actinic keratosis, acne, psoriasis, ichthyoses and other keratinization and hyperproliferative disorders of the skin, Darrier's disease or skin cancer (see Vuligonda et al., col.1, lines 32-59), that are associated with hyperproliferation or keratinization.

For these reasons, rejection of the present claims over Bandman et al. (U.S. Patent No. 5,858,750; 1999) in view of Vuligonda et al. (U.S. Patent No. 5,917,082; 1999) is not made.

### *Conclusion*

Allowability of the instant claims as indicated in the previous Office Action dated February 10, 2005 has been regrettably withdrawn in light of the above rejections.

Claim 43 would otherwise be considered allowable, but is objected to for the fact that it depends from a rejected base claim.

Rejection of claims 40-42 is deemed proper.

No claims of the present application are allowed.

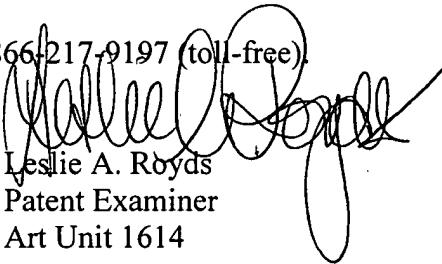
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie A. Royds  
Patent Examiner  
Art Unit 1614

October 27, 2005



CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600